

Alty Dkt. No.: 1490DIV USSN: 09/854,124

### REMARKS

Claims 28-36 are pending after entry of the amendments set forth herein.

Claims 34-36 are new. Claims 34-36 correspond exactly to Claim 20-22, as originally filed. Accordingly, no new matter is added by these new claims.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

## The new claims

The new claims correspond exactly in their wording to cancelled claims 20-22 (corresponding to Claim Group III of the Restriction Requirement dated September 24, 2002).

The Applicants respectfully submit that there can be no question that these new claims correspond to the subject matter of Claim Group III since their wording is exactly the same as claims 20-22, the subject matter encompassed by Claim Group III.

The new claims were presented solely in the interest of expediting prosecution, and are not to be construed as an acquiescence to the correctness of the assertions made in the Office Communication mailed January 21, 2003.

As is detailed below, the Applicants respectfully submit that claims 28-33 correspond to the subject matter of Claim Group III, and that the restriction requirement between Claim Groups I, III and IV should be withdrawn.

## The Office Communication

The Restriction Requirement dated September 24, 2002 required election of one Group from claim Groups I-VI.

In the response to that Restriction Requirement, the Applicants provisionally elected claim Group III and simultaneously canceled claims 20-22 (corresponding to claim Group III) and added new claims 28-33. The response stated at the bottom of page 4 that "The newly presented claims 28-33 correspond to subject matter of Group III".

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The Office communication mailed January 21, 2003 stated that the response is non-responsive to the prior Office Action because although Applicant elected Group III, the claims of Group III have been canceled.

Applicants respectfully submit that their response was completely responsive to the prior Office Action, and that no further action by the Applicants is necessary prior to examination of the claims.

## Interview

The Applicants wish to extend their gratitude to Examiner Caputa for the interview on February 4, 2003 with the Applicants' representative James Keddie.

Applicants discussed the question of whether new claims 28-33 correspond to the subject matter of provisionally elected Group III, and discussed the traversal of the Restriction Requirement. Examiner Caputa requested the Applicants respond to the communication from the Examiner mailed January 21, 2003, and further explain a) why new claims 28-33 correspond to the subject matter of provisionally elected Group III, and b) why claim Groups I, III and V should not be the subject of a Restriction Requirement.

# New claims 28-33 correspond to the subject matter of elected Group III

In the response to the Restriction Requirement dated September 24, 2002, the Applicants provisionally elected claim Group III.

Claim Group III is described in the Restriction Requirement as follows:

Group III: Claims 20-22 are drawn to detection of a concerous colon cell comprising assaying the level of expression of SEQ ID NO:5 in a test colon cell compared to a cancerous colon cell classified in Class 435, subclass 6.

Claims 20-22 were inserted by Preliminary Amendment on May 10, 2001. Claims 21-22 are dependent on claim 20. Claim 20 is as follows:

-20. (New) A method for detecting a cancerous colon cell comprising:



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detecting expression of a gene in a test colon cell, wherein the gene comprises a sequence of SEQ 1D NO:5; and

comparing a level of expression of the gene in the test colon cell with a level of expression of the gene in a control colon cell, wherein the control colon cell is a cancerous colon cell;

wherein where the level of expression of the gene in the test colon cell relative to the level of expression in the control colon cell is similar indicates that the test colon cell is cancerous.--

Claims 20-22 were canceled, and claims 28-33 were added by Preliminary Amendment on November 15, 2002. Claims 29-33 are dependent on claim 28. Claim 28 is as follows:

--28. (New) A method for detecting a cancerous colon cell, said method comprising: comparing a level of expression of a CGI-122 gene product in a test colon cell with a level of expression of a CGI-122 gene product associated with a control colon cell, wherein said control colon cell is a cancerous colon cell;

wherein a level of expression of a CGI-122 gene product in a test colon cell that is similar to a level of expression of a CGI-122 gene a control colon cell indicates that said test colon cell is cancerous. —

An inspection of the preambles and bodies of canceled claims 20 and new claim 28 shows that they are both directed to methods of detecting a cancerous colon cell by comparing the level of a gene product (SEQ ID NO:5 corresponds to CGI-122; see Table 4 on page 59) in a test colon cell to a control level of the gene product.

In other words, canceled claim 20 and new claim 28 are both drawn to detection of a cancerous colon cell comprising assaying the level of expression of a gene product identified by SEQ ID NO:5 (CGI-122 being the gene product identified by SEQ ID NO:5) in a test colon cell compared to a cancerous colon cell. The Applicants merely replaced claims 20-22 with another set of claims corresponding to the same subject matter.

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Applicants are not aware of any rule or examining procedure that prevents a group of claims corresponding to a restriction group from being replaced by a different set of claims corresponding to the same subject matter in response to a Restriction Requirement. It is Applicant's understanding that such amendments are common practice.

Applicants respectfully submit that the subject matter of the new claims corresponds to the subject of claim Group III, and that the response filed on November 21, 2002 is completely responsive to the prior Office Action.

## Applicants further traverse the restriction of Groups I, III and V

Claim Groups I, III and V, are described in the Restriction Requirement as follows:

Group I: Claims 16-18 are drawn to detection of a cancerous colon cell comprising assaying the level of expression of SEQ ID NO:6 in a test colon cell compared to a cancerous colon cell classified in Class 435, subclass 6.

Group III: Claims 20-22 are drawn to detection of a cancerous colon cell comprising assaying the level of expression of SUQ ID NO:5 in a test colon cell compared to a cancerous colon cell classified in Class 435, subclass 6.

Group V: Claims 24-26 are drawn to detection of a cancerous colon cell comprising assaying the level of expression of SEQ ID NO: 7 in a test colon cell compared to a cancerous colon cell classified in Class 435, subclass 6.

As such, each of the claim groups assertedly corresponds to methods involving assaying the level of expression of SEQ ID: 5, 6 or 7, in cells. The Groups are assertedly different because they assay the expression of different sequences (SEQ ID NOS:5, 6 and 7).

However, the Applicants note that claims 16, 20 and 24 (the independent claims for each claim group), each recite methods involving assaying the expression of a gene in a test colon cell, where the gene comprises a sequence of SEQ ID NO:6, 5 and 7, respectively. As such, the Restriction Requirement is not accurate in stating that each of the claims groups is directed to methods involving assaying the level of expression of SEQ ID NOS;5, 6 or 7 in cells. Rather, each of the claim groups is

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directed to methods involving assaying the level of expression a gene comprising the sequence of SEQ ID NOS:5, 6 or 7 in cells.

As established in Table 4 on page 59 of the instant application, SEQ ID NOS:5, 6 and 7 each correspond to the CGI-122 gene, and a sequence alignment of SEQ ID NOS:5, 6 and 7 and CGI-122 was provided with the response to the Restriction Requirement (and is submitted herewith).

Since claims 16, 20 and 24 are each directed to methods involving assaying the level of expression of genes comprising the sequence of SEQ ID NOS:5, 6 or 7 in cells, and SEQ ID NOS:5, 6, and 7 all correspond to the CGI-122 gene, then claims 16, 20 and 24 all correspond to a method involving assaying the level of expression of CGI-122 in cells. As such, there can be no undue burden on the Examiner because all of the relevant art can be identified by searching for art relating to a single gene.

According to MPEP § 803, claims may only be restricted if the inventions are independent or distinct, or there is a serious burden on the Examiner. The Applicants respectfully submit that the subject matter claimed in Groups I, III and V would not represent an undue burden on the Examiner because the claim Groups are directed to methods each involving assaying the level the same gene, CGI-122.

Applicants respectfully submit that the subject matter of Groups I, III and V can be examined in a single application, and, accordingly, Applicants respectfully request withdrawal of the Restriction Requirement for Groups I, III and V.

Applicants note a provisional election to prosecute the subject matter of Group III was made in the response to the Restriction Requirement. Applicants submit that should this traversal prove unsuccessful, the new claims may be examined with respect to SEQ ID NO:5.

### CONCLUSION

The applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at (650) 833 7723.

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The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50 0815 Order No. 2300-1490DIV.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

Date: Feb. Nony 21, 2003

By:

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#### APPENDIX A: Genbank Accession number AF151880

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